

REMARKS

This Amendment substantially incorporates the substance of a telephonic interview on January 15, 2009 ("the interview") between the Examiner, a primary examiner, the undersigned, and Lindsay Heller, attorney for the law firm of record. The undersigned wishes to thank the Examiner for his time spent preparing for and conducting the interview. The undersigned initiated the interview to discuss the Office action dated September 18, 2008. During the interview, the participants discussed possible claim amendments. No agreement was reached.

In addition, there was some discrepancy between the Office action summary and the detailed action. The Office action summary indicated that claims 1, 14, and 20-23 were rejected while the detailed action indicated that claims 1, 13, and 20-23 were rejected. The Examiner stated that the detailed action was correct.

Claim 13 has been amended. Claims 41-46 have been added. Claims 1-12, 14-19, and 24-40 have been cancelled without prejudice. With entry of this Amendment, claims 13, 20-23, and 41-46 will be pending.

Support for amended claim 13 can be found at least on page 1 of the specification. Support for claim 41 can be found at least on pages 1, 8, and 9 of the specification. Support for claim 42 can be found at least on pages 1, 8, and 18 of the specification. Support for claims 43-46 can be found at least on pages 3, 4, and 18 of the specification. No new matter has been added. The Applicant respectfully submits that the claims are in condition for allowance.

Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Schmidbaur et al. (*Zeitschrift fuer naturforschung teil B anorganische chemie Organische Chemie* (1978) 33:1325-1329) ("Schmidbaur").

Claims 1, 13, and 20-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vicente et al. (*Journal of Organometallic Chemistry* (2002) 663:40-45) ("Vicente") in view of Schmidbaur.

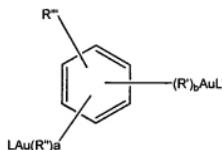
Claims 14 and 24 were objected to as being dependent upon a rejected base claim and have been cancelled without prejudice. Claims 41 and 42 have been added and substantially comport to the scope of cancelled claims 14 and 24. Therefore, consideration and allowance of claims 41-46 are respectfully requested.

Claim 1 has been cancelled, and therefore the rejection to claim 1 is now moot.

Independent Claim 13 and Dependent Claims 14 and 20-24

Independent claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Vicente in view of Schmidbaur.

Claim 13 recites: A pharmaceutical composition for the treatment of cancer comprising an effective amount of a compound having two gold(I) atoms each covalently bonded to a carbon atom in a covalent link connecting the two gold(I) atoms, wherein said compound has the formula:



where: L and L' are ligands; R' and R'' are substituted or unsubstituted divalent hydrocarbon moieties; a is 0 to 3; b is 0 to 3; R''' is H, SO₃⁻, PO₄²⁻, CO₂H, OH, (CH₂)_nCH₃, O(CH₂)_nCH₃, S(CH₂)_nCH₃, or NR''''C(O)(R''''') where R'''' and R''''' are (CH₂)_nCH₃; and n is 0 to 6; and a pharmaceutically acceptable excipient."

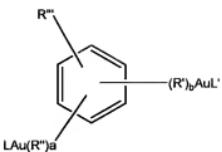
Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Schmidbaur discloses “[a] series of ionic phosphorus ylide complexes of gold(I) halides . . .” Schmidbaur states that “[t]he compounds are of the type $[R_3PAu-CH_2PR_3]^+Cl^-$, R = C₂H₅, and $[(R_3PCH_2)_2Au]^+X^-$, where R = CH₃, C₂H₅, n-C₄H₉, C₆H₅, and X = Cl, Br (1-6). Along with a cyclic complex $[(C_2H_5)_2P(CH_2)_2Au]_2$ (7) these materials have been tested in a pharmacological study for a possible use in an oral arthritis therapy.” Schmidbaur, Abstract. Schmidbaur states that “[c]ompounds 1 and 5-7 showed no or only negligible effects on Adjuvans-arthritis induced in rats, while 3 and 4 were very toxic. Complex 2 was comparable to standard chrysotherapeutic agents in a preliminary study, but a more detailed investigation including LD₅₀ tests for mice showed too narrow a gap between its toxic and therapeutically useful doses.” Schmidbaur, Abstract.

Vicente states that “[m]etal complexes with bridging –C ≡C(Ar)C ≡C- spacers (Ar being various aromatic rings) have been shown to display electrical conductivity, nonlinear optical or liquid crystalline properties [1]. Among them, all the reported gold complexes are neutral which is also the case for the vast majority of alkynylgold(I) complexes. So far, arenediethynylgold(I) complexes of the types . . . have been described. . . . Three of them [3,6] have been studied by X-ray diffraction methods and all show infinite chain or ribbon structures and display interesting photophysical properties [6,7].” Vicente, p. 1. Vicente also states: “In this paper we report mono-, di-, tri-, and polyanionic alkynylgold(I) complexes of the types . . . that we have prepared with the aim of extending the short family of anionic alkynylgold(I) complexes and with the hope of finding among them some peculiar structural features.” Vicente, p. 1.

One of skill in the art would not be motivated to combine Schmidbaur and Vicente for the following reasons.

Schmidbaur does not teach or suggest “[a] pharmaceutical composition for the treatment of cancer comprising an effective amount of a compound having two gold(I) atoms each covalently bonded to a carbon atom in a covalent link connecting the two gold(I) atoms, wherein said compound has the formula:



where: L and L' are ligands; R' and R'' are substituted or unsubstituted divalent hydrocarbon moieties; a is 0 to 3; b is 0 to 3; R''' is H, SO₃⁻, PO₄²⁻, CO₂H, OH, (CH₂)_nCH₃, O(CH₂)_nCH₃, S(CH₂)_nCH₃, or NR'''C(O)(R''') where R''' and R''' are (CH₂)_nCH₃; and n is 0 to 6; and a pharmaceutically acceptable excipient."

Vicente makes no mention of any pharmaceutical compositions whatsoever. The Examiner himself states that “Vicente et. al. [does] not teach a pharmaceutical composition of [M-1,3-pheylenedi-2,1-ethynediyl]bis(triphenylphosphine)di-Gold. . . .” Office action, p. 6. In fact, Vicente discloses that the compounds taught therein “display electrical conductivity, nonlinear optical or liquid crystalline properties,” and that they “display interesting photophysical properties.” Vicente, p. 1. One of skill in the art would not look to Vicente for pharmaceutical compositions. Schmidbaur, on the other hand, as its title suggests, is directed to “some gold(I) complexes of phosphorus ylides and their effect in gold therapy with the adjuvans arthritis model.” Schmidbaur, Title. Accordingly, the Applicant respectfully submits that, without the benefit of impermissible hindsight, it would be quite a leap for one of skill in the art considering Vicente (which again, is directed to non-pharmaceutical applications such as electrical conductivity) to somehow be motivated to jump to Schmidbaur (which again, is specific to arthritis). The Examiner has not identified any reason why one of skill in the art would be motivated to combine the teachings of Schmidbaur and Vicente to arrive at the claimed pharmaceutical compositions. Citing *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006), the Supreme Court clarified that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). See also MPEP 2141. The Examiner is reminded that it is “important

to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007).

Furthermore, one skilled in the art would not combine Vicente with Schmidbaur due to the unpredictability in the effects of Schmidbaur’s compounds. Schmidbaur states that “[c]ompounds 1 and 5-7 showed no or only negligible effects on Adjuvans-arthritis induced in rats, while 3 and 4 were very toxic. Complex 2 was comparable to standard chrysotherapeutic agents in a preliminary study, but a more detailed investigation including LD₅₀ tests for mice showed too narrow a gap between its toxic and therapeutically useful doses.” Schmidbaur, Abstract. Therefore, these results would lead one of skill in the art away from the use of these types of compounds in pharmaceutical compositions.

In view of the foregoing, independent claim 13 is allowable. Consideration and allowance of independent claim 13 are respectfully requested.

Claims 14 and 20-24 depend from allowable claim 13 and therefore are allowable. In addition, claims 14 and 20-24 may contain additional patentable subject matter for reasons that may not be discussed herein. Allowance of these claims is respectfully requested.

Independent Claims 41 and 42 and Dependent Claims 43-46

Claims 14 and 24 were objected to as being dependent upon a rejected base claim and have been cancelled without prejudice. Claims 41 and 42 have been added and substantially comport to the scope of cancelled claims 14 and 24. In view of the foregoing, independent claims 41 and 42 are allowable. In addition, claims 41 and 42 may contain additional patentable subject matter for reasons that may not be discussed herein. Consideration and allowance of independent claims 41-42 are respectfully requested.

Claims 43-46 ultimately depend from allowable claim 42 and therefore are allowable. In addition, claims 43-46 may contain additional patentable subject matter for reasons that may not be discussed herein. Allowance of these claims is respectfully requested.

CONCLUSION

In view of the foregoing, allowance of the application is respectfully requested. The Examiner is strongly encouraged to contact the undersigned by telephone at the Examiner's convenience should any issues remain.

Respectfully submitted,

/gregory j. hartwig/

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